Complete Summary

GUIDELINE TITLE

Use of botanicals for management of menopausal symptoms.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Use of botanicals for management of menopausal symptoms. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Jun. 11 p. (ACOG practice bulletin; no. 28). [56 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Menopausal symptoms including vasomotor symptoms (such as hot flashes, flushes, and night sweats); sleep, mood and affective, cognitive, and other behavioral disorders; loss of libido, vaginal dryness, and dyspareunia; and menstrual disorders/menorrhagia
- Coronary heart disease
- Osteoporosis

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling

CLINICAL SPECIALTY

Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To examine available scientific information on alternative therapies for treatment of menopausal symptoms and provide recommendations on efficacy and potential adverse consequences

TARGET POPULATION

Women experiencing menopausal symptoms

INTERVENTIONS AND PRACTICES CONSIDERED

1. Counseling patients about the relative risks and benefits of conventional therapies and alternative interventions
2. Use of botanicals in menopausal women
    - Short-term (≤2 years) soy and isoflavones treatment of vasomotor symptoms and prolonged periods of soy and isoflavone intake to improve lipoprotein profiles and protect against osteoporosis
    - Short-term (≤2 years) St. John´s wort treatment of mild to moderate depression
    - Short-term (≤6 months) black cohosh treatment of vasomotor symptoms
    - Note: Other botanicals such as evening primrose, dong quai, ginseng, valerian root, chasteberry or vitex, and wild or Mexican yam were considered but not recommended.
3. Documenting adverse events and outcomes in the patient´s chart, discontinuing therapy if adverse events occur, and reporting them to the U.S. Food and Drug Administration

MAJOR OUTCOMES CONSIDERED

Risks and benefits of botanicals

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 2001. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and subspecialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

Given the general lack of standardization of products, the relatively short duration of therapy and follow-up in the available data, and the difficulty of interpreting the available clinical data, few recommendations can be made with confidence. The following conclusions can be drawn in reference to short-term (≤2 years) use of botanical and alternative medicine for the management of menopause.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Soy and isoflavones may be helpful in the short-term (≤2 years) treatment of vasomotor symptoms. Given the possibility that these compounds may interact with estrogen, these agents should not be considered free of potential harm in women with estrogen-dependent cancers.
- St. John's wort may be helpful in the short-term (≤2 years) treatment of mild to moderate depression in women.
- Black cohosh may be helpful in the short-term (≤6 months) treatment of women with vasomotor symptoms.
- Soy and isoflavone intake over prolonged periods may improve lipoprotein profiles and protect against osteoporosis. Soy in foodstuffs may differ in biological activity from soy and isoflavones in supplements.

Counseling Patients about Complementary and Alternative Medicine

- All patients should be asked about their use of herbal therapies and dietary supplements. Use of these products should be documented in the patient's chart.
- "Natural" is not an assurance of safety or efficacy.
- Potentially dangerous drug-herb interactions occur*.
- Lack of standardization of botanicals may result in variability of content and efficacy from batch to batch, from a single manufacturer, or between manufacturers.
- Lack of quality control and regulation may result in contamination, adulteration, or potential misidentification of plant products.
- Errors in compounding may result in toxic or lethal outcomes in custom-blended herbal preparations.
- Botanicals should not be used by women planning to become pregnant in the near future or during pregnancy or lactation without professional advice.
- Botanicals should not be taken in larger than recommended doses or for longer than recommended duration.
- Several botanicals have known adverse effects and toxicities.
- Infants, children, and the elderly should not use botanicals without professional advice.
- Patients should be counseled in a rational, judicious, and balanced manner about the relative risks and benefits of conventional therapies and alternative interventions.
- Adverse events and outcomes should be documented in the chart, therapy discontinued, and reported to the U.S Food and Drug Administration.
- Because the expected placebo response for menopausal treatment ranges from 10% to 30%, a small positive response to any treatment, conventional or alternative, may not necessarily represent a pharmacologic effect. Anecdotal experience is not a substitute for well-constructed clinical trials.

Nonetheless, the effect of support, counseling, and empathetic care should not be discounted or dismissed.

*For a complete listing of potentially dangerous drug-herb interactions see Newall CA, Anderson LA, Phillipson JD. Herbal medicines: a guide for health-care professionals. London: Pharmaceutical Press, 1996.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendation

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved knowledge regarding efficacy and potential adverse consequences of botanical medicine

POTENTIAL HARMS

Adverse Effects of Specific Botanicals:

- Soy and isoflavones. Given the possibility that these compounds may interact with estrogen, these agents should not be considered to be free of potential harm in women with estrogen-dependent cancers.
- St. John's wort. Side effects are similar to, but far less than those of standard antidepressant medications, including dry mouth, dizziness, and constipation.

  St. John's wort is potentially photosensitizing, and concern has been raised about an increased rate of cataracts. The issue of possible interactions between St. John´s wort and selective serotonin reuptake inhibitors or monoamine oxidase inhibitors has been raised. Some consultants advise against using St. John´s wort for weeks to months after stopping these drugs. Interaction with anesthetic agents has also been reported.

- Black cohosh. The only side effect of black cohosh is occasional gastric discomfort.

CONTRAINDICATIONS

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Botanicals should not be used by women planning to become pregnant in the near future or during pregnancy or lactation without professional advice.

Infants, children, and the elderly should not use botanicals without professional advice.

QUALIFYING STATEMENTS

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These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jun

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 22, 2004. The information was verified by the guideline developer on December 9, 2004.

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